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| In re Application of | : |
| Teresa Mujica-Fernaud et al | : |
| Serial No.: 10/725,349 | : PETITION DECISION |
| Filed: December 2, 2003 | : |
| Attorney Docket No.: MERCK-2805 | : |

This is in response to the petition under 37 CFR 1.144, filed January 13, 2006, requesting withdrawal of a restriction requirement.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 and contained claims numbered 1-33. In a first Office action, mailed March 7, 2005, the examiner set forth a restriction requirement, as follows:

- Group I, claims 1-7, drawn to compounds, compositions and method if making;
- Group II, claims 8-21, 24-27 and 30 drawn to methods of use;
- Group III, claim 22, drawn to a composition with additional ingredient;
- Group IV, claim 23, drawn to a kit;
- Group V, claim 28, drawn to food equipment;
- Group VI, claims 29 and 31-32, drawn to a cosmetic composition;
- Group VII, claim 33, drawn to a compound of Formula VI.

The examiner reasoned that the Groups were drawn to different classes of invention and thus independent and distinct. The examiner also argued that there were several methods of use and that there was a burden on the Office to examine all of them. The examiner also advised of rejoinder if product claims were elected and found allowable.

Applicants replied on March 23, 2005, electing Group I, with traverse, and acknowledging that rejoinder would be proper when the product claims were found allowable.

The examiner mailed a new Office action to applicants on April 21, 2005, noting the traversal and maintaining that the requirement for the reasons of record and making it Final. However, the method claims of Group II were rejoined based on allowability of the composition claims. The

requirement was also modified by holding that claim 24 should have been grouped with claim 22 and claim 30 should have been grouped with claim 29. Claims 8-21 and 25-27 were then rejected under 35 U.S.C. 112, first paragraph, as lacking enablement.

Applicants replied on July 21, 2005, by adding claim 34 and responding to the examiner's maintaining the restriction requirement Final arguing the requirement improper based on combination-subcombination relationship. Applicants also argued the rejection of record.

The examiner mailed a new non-Final Office action to applicants on October 27, 2005, maintaining the restriction requirement and maintaining the rejection under 35 U.S.C. 112, first paragraph, for lack of enablement for claims 8-13, 17-20 and 26-27.

Applicants replied on January 13, 2006, by filing an amendment canceling claims 8-10, 12-13, 17, 19-20 and 26-28, and by amending claims 18 and 21 and responding to the rest of the Office action properly. This petition was filed concurrently, requesting withdrawal of the restriction requirement with respect to claims 22-25 and 28-32.

The examiner mailed a non-Final Office action to applicants on May 2, 2006, maintaining the rejection of claims 11, 14-16, 18 and 20 under 35 U.S.C. 112, first paragraph, for lack of enablement.

DISCUSSION

Applicants argue in their petition that claims 22-25 and 28-32 are improperly withdrawn by restriction. Applicants argue that these claims are in a combination-subcombination relationship with claims 1, 7 or 11 from which they depend and that the examiner has failed to meet the requirements of two-way distinctness for maintaining such a restriction requirement.

A review of the examiner's original requirement shows that these claims were placed in Groups III –VII and classified in various other classes and were held as separate and distinct inventions based, in part, on such classification and that they related to distinct products, not just the basic chemical compound or composition.

A review of the withdrawn claims still pending, shows that claims 22 and 23 are directed to the pharmaceutical composition (of claim 7) combined with a second (unnamed) pharmaceutically active compound. Any patentability of the combination cannot be ascribed to the second component, but lies solely with the primary compound which the examiner has determined to be patentable. The patentability of the subcombination compound imparts patentability to the combination of the compound and additional component insofar as prior art is concerned. Thus no two-way distinctness is or can be shown. The restriction of these claims is withdrawn.

In like manner claims to a food supplement comprising the compound (claim 29) or a cosmetic composition containing the compound (claims 30-32) are also combinations in which patentability over the prior art is dependent solely on the subcombination compound's patentability over the prior art. No two-way distinctness has or can be shown to justify such restriction. The restriction of these claims is withdrawn.

However claims 24 and 25 which depend from claim 11 do not appear to fit the above criteria. Claim 11 is a method of treating various conditions or diseases using the pharmaceutical composition of claim 7. Claim 25 is directed to performing radiotherapy. Radiotherapy is a treatment which can be administered in the presence or absence of the pharmaceutical composition, thus showing two-way distinctness and proper restriction. Claim 24 comprises administering additional compounds, such as modulators and inhibitors. These appear to be administered separately from the pharmaceutical composition and to be unrelated to its use. No connection or coaction between the additional compounds and the basic pharmaceutical composition is stated. Thus two-way distinctness is evident in that these compounds do not depend on the pharmaceutical composition for patentability as they are separately patentable. For this reason these claims are not rejoined.

DECISION

The petition is **GRANTED-IN-PART**. Claims 22-23 and 28-32 are rejoined as improperly restricted based on lack of two-way distinctness between the combination and subcombination. Claims 24-25 are not rejoined as being properly restricted based on two-way distinctness between combination and subcombination.

In view of this decision the application will be returned to the examiner for preparation of a new action on the merits not inconsistent with this decision. The Office action mailed May 2, 2006, is vacated as incomplete in view of this decision.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.



George C. Elliott
Director, Technology Center 1600